

in-part application has been filed with the application. Enclosed is a copy of that declaration, dated February 17, 1998.

The 35 U.S.C. §112 Rejection

Claim 12 was rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The rejection is respectfully traversed.

Claim 12 has been amended to recite inhibition of cancer cell growth in a host. The specification has shown that treatment with the immunotoxin disclosed in the instant invention inhibited the growth of neoplastic cells in mice (see Example 14). Accordingly, Applicant respectfully submits that the rejection of claim 12 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 8-15 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite because claim 8 is dependent on non-elected claim 6. Claim 8 has been amended to become an independent claim that incorporates the limitations of the non-elected claim 6. Accordingly, Applicant respectfully submits that the rejections of claims 8-15 under 35 U.S.C. §112, second paragraph, be withdrawn.

Claim 12 was rejected under 37 C.F.R. 1.75(c) for failing to further limit the subject matter of a previous claim. Claim 12 has been amended to recite inhibition of cancer cell growth in a host, thereby further limit "treating" in previous claim. Accordingly, Applicant respectfully submits that the rejections of claims 12 under 37 C.F.R. 1.75(c) be withdrawn.

The 35 U.S.C. §103(a) Rejection

Claims 8-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over **Tanimoto** et al. or **Scheinberg** et al. in view of **Thorpe** et al., **Andrews** et al. and **Rosenblum** et al. These rejections are respectfully traversed.

Tanimoto et al. and **Scheinberg** et al. teach an anti-CD33 monoclonal antibody M195. **Thorpe** et al. teach conjugation of antibodies to gelonin. **Andrews** et al. teach anti-CD33 antibodies may be useful for the treatment of leukemia. **Rosenblum** et al. teach the sequence of gelonin. Nevertheless, Applicant respectfully submits that combining these references does not lead to the claimed invention, nor do they encompass all the important features of the present invention.

Although the references teach M195 and gelonin, they do not teach or suggest M195 conjugated to recombinant gelonin. **Tanimoto et al., Scheinberg et al., Thorpe et al. and Andrews et al.** do not teach or suggest the making and using of M195 conjugated to recombinant gelonin, whereas **Rosenblum et al.** do not teach or suggest conjugating recombinant gelonin to M195 for cancer treatment. Thus, the combined teaching from these references would not result in the present invention. Furthermore, the therapeutic efficacy of the M195-recombinant gelonin conjugate is not taught, suggested or shown in any cited references. In contrast, the present invention has detailed disclosure on the effectiveness of the M195-recombinant gelonin conjugate *in vitro* (Examples 9, 10) and *in vivo* (Example 14). Applicant also has evidence that indicate efficacy and lack of significant toxicity of the M195-recombinant gelonin conjugate in clinical setting. The combined references do not teach or suggest that Applicant's specific conjugate would be effective and non-toxic.

Hence, Applicant respectfully submits that no teaching, suggestion or incentive may be gleaned from the references, individually or together, with regard to the making and using of the claimed invention. The invention as a whole is not *prima facie*

obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, Applicant respectfully submits that the rejection of claims 8-15 under 35 U.S.C. §103(a) be withdrawn.

Claims 8-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over **Scheinberg** (U.S. patent 5,730,982) in view of **Thorpe** et al., **Andrews** et al. and **Rosenblum** et al. These rejections are respectfully traversed.

U.S. patent 5,730,982, issue to **Scheinberg**, teaches the use of M195-radioisotopes conjugates in cancer treatment. The cited patent does not teach, suggest or show data on the making and using M195-recombinant gelonin conjugate in cancer treatment. **Thorpe** et al., **Andrews** et al. and **Rosenblum** et al. have been discussed above.

Similar to the argument above, Applicant submits that the combined references do not teach, suggest or provide the requisite incentive that touch upon the claimed invention of M195-recombinant gelonin conjugate, nor does it encompass all the important features of the present invention as discussed above. Thus the invention as a whole is not *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Accordingly, Applicant respectfully submits that the rejection of claims 8-15 under 35 U.S.C. §103(a) be withdrawn.

This is intended to be a complete response to the Office Action mailed December 27, 1999. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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